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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation LISA HYDE and MARK HYDE, a married couple, Plaintiff, v. C.R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, an Arizona corporation, Defendants.	No. MD-15-02641-PHX-DGC **PLAINTIFFS' MOTION *IN LIMINE* #5 TO EXCLUDE EVIDENCE OF SOCIETY OF INTERVENTIONAL RADIOLOGIST ("SIR") "GUIDELINES"** (Assigned to the Honorable David G. Campbell) (Oral Argument Requested)

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MEMORANDUM OF LAW IN SUPPORT

Plaintiffs seek a pretrial ruling excluding the 2003 Grassi article published by the Society of Interventional Radiologist ("SIR"); the "Guidelines".[1] Based on the two previous trial records, Defendants' use of this evidence is inappropriate because the failure to warn claims have been dismissed in this case. Plaintiffs move to exclude this evidence entirely.

[1] Plaintiffs are neither "re-urging" nor seeking re-consideration of the Court's previous Order regarding trade associations (Doc. 10258), but seek review of specific evidence for the *Hyde* trial since the Court's ruling on Defendants' Motion for Partial Summary Judgment (Doc. 12007).

I. The SIR Guidelines Are Not Relevant Under Wisconsin Law

Since Plaintiffs' failure to warn claims were dismissed, the purposes for which the SIR Guidelines were previously admitted - to show notice to, and knowledge of the Guidelines in the medical community - are no longer relevant. What was known to the medical community via these Guidelines neither proves nor disproves a material fact related to Plaintiffs' design defect case and renders the evidence irrelevant. Fed R. Evid. 401, 402.[2] The Guidelines neither present nor provide a defense to a safer alternative design. WI. Stat. § 895.047(1)(a). As such they are not relevant and should be excluded so as not to confuse or mislead the jury and prejudice Mrs. Hyde's surviving claims. Fed. R. Evid. 401, 402, 403.

Moreover, in Wisconsin, a product's design is unreasonably dangerous if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design and the omission of such renders the product not reasonably safe. WI. Stat. § 895.047(1)(b). A product is not reasonably safe under Wisconsin law if it is "in a condition not contemplated by the ultimate consumer." *Green v. Smith & Nephew AHP, Inc.*, 245 Wis. 2d 772, 825-26 (Wis. 2001)(citing *Vincer v. Esther Williams All-Aluminum Swimming Pool Co.*, 69 Wis. 2d 326, 332, (Wis. 1975). There is no learned intermediary defense where there is no failure to warn allegation. The learned intermediary doctrine excuses the manufacturer of a product from having to warn consumers of the products adverse effects; it need warn only physicians. *Walton v. Bayer Corp.*, 643 F.3d 994, 999–1000 (7th Cir. 2011).

Any evidence of rates of historical complications in the SIR Guidelines have no

[2] Even if the evidence was relevant, the two previous trials have revealed these so-called thresholds and trackable events are not meant to endorse or demean the design and/or failure rates of any particular device – especially the Bard device that is the subject of the *Hyde* case and therefore would be highly prejudicial. Fed. R. Evid. 403. No expert in the previous trials has testified that the complication rates reported in 1970's, 1980's and 1990's articles are "acceptable" to anyone, and certainly does not speak to the entirety of the medical community implanting IVC filters more than 10 years after the references cited in this 2003 article.

effect on the jury deciding if Mrs. Hyde's filter departed from its intended design, or if known complications could have been avoided by adopting an alternative design. Known complications, such as those listed in the SIR Guidelines, are just that – known. The question now is whether or not those known complications could have been avoided entirely or lessened by Bard's adoption of a reasonable alternative design – something not addressed in these "guidelines."

Assuming *arguendo*, that the SIR Guidelines do in fact set a standard of complication rates that manufacturers must measure themselves against, it *still* would be irrelevant to a design defect case. If a reasonable, safer alternative could have prevented Mrs. Hyde's injuries, then Bard is liable for design defect and her injuries and damages, regardless of whether they met any standards supposedly set by the SIR, which they do not.

Moreover, if the evidence was relevant, the use of the evidence to show what the medical community knew does not get Bard past the last hurdle; there is no testimony supporting that the rates in the text are actually acceptable. Dr. Clement Grassi, lead author of the Guidelines article as existed at all relevant times applicable to the subject Bard device, and who has been a paid litigation expert for Bard for many years and many prior cases, affirmed at trial his prior deposition testimony that:

1. He and his fellow authors do not imply that rates in the (threshold and reported) range are acceptable.
2. The Guidelines were not intended as instruction manual for manufacturers and their failure rates.
3. The Guidelines not create safety thresholds relating to for failure modes associated with Bard's filters.[3]

This has been confirmed in that the "Guidelines" were recently updated to state: "The following events may or may not be clinically significant in a particular patient. For

[3] Ex. A, *See Jones v. Bard* Trial Transcript at 1554:10 – 1555:7; Ex. B, *See also, Booker v. Bard* Trial Transcript at 1994:7-1997:20 and 2006:12-19

this reason, threshold for these events are not included in this document…the data in the table represents reported outcomes from various publications and not the SIR standard for complications." *See* 2016 Quality Improvement Guidelines, p. 13.

Accordingly, in this case, sans a failure to warn cause of action, any perceived probative value that might attach to anything within this article (a notion rejected by the lead author per the above-described testimony) is overwhelmed by the prejudice, confusing, misleading and irrelevant content, intent and nature of any iteration of these alleged Guidelines. Fed. R. Evid. 403. There simply can be no place for these guidelines in a case that no longer involves a failure to warn cause of action, and where the focus will be on Wisconsin design defect law.

For the above stated reasons, Plaintiffs respectfully request that evidence regarding the Society of Interventional Radiologist ("SIR") "Guidelines" be excluded.

RESPECTFULLY SUBMITTED this 10th day of August 2018.

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By:*/s/ Mark O'Connor*

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CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of August 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Jessica Gallentine